DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 30, 2014

Dickson & Dickson Healthcare (US) Incorporated
% Ragunath Muniandy
Black Diamond Video Incorporated
503 Canal, Boulevard
Richmond, California 94804

Re: K142076
Trade/Device Name: ClaveGuard Freedom Surgical Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: May 30, 2014
Received: August 4, 2014

Dear Muniandy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.09.30 17:27:22 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142076

Device Name

ClaveGuard Freedom Surgical Light

Indications for Use *(Describe)*

The Claveguard Freedom Surgical Light is designed to illuminate the surgical site in Operating theatres

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

Date Prepared: 05/30/2014

510K Owner:	ClaveGuard Pty, Ltd Unit 3, 40 Brodie St, Rydalmere, NSW 2116, Australia.
Contact:	Ragunath Muniandy Regulatory Affairs Specialist 503 Canal Blvd, Richmond, CA 94804
Trade Name:	ClaveGuard Freedom surgical light
Common Name:	Surgical Light
Classification Name :	Light, Surgical Accessories
Classification Panel:	General and Plastic Surgery
CFR section:	21 CFR 878.4580
Class:	2
Product Code:	FSY
Predicate Device:	Berchtold Chromophare E668 (K090378)
Device Description:	The ClaveGuard Freedom surgical lights are suitable for all types of surgical procedures in operating rooms. The light is based on Light Emitting Diodes (LEDs) in combination with adaptive focus and shadow free illumination. It operates at a distance of 70-140cm from the surgical site. A light system may consist of 1 to 3 light heads supported by pivoting suspension system that is mounted to Healthcare facility's ceiling. The system may include optional monitor extension arms, monitor mounts, and in-light video camera.

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Indications for use: The ClaveGuard Freedom surgical light is designed to illuminate the surgical site in Operating theatres.

Substantial Equivalence (SE) Rational: The ClaveGuard Freedom surgical light is substantially equivalent to predicate devices since intended use, operational principle, basic technology and design are similar. The minor differences between the ClaveGuard Freedom surgical lights and predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended of use of the device. Therefore based on the applicable testing and the equivalence information presented in this submission, Claveguard Pty Ltd. believes that ClaveGuard Freedom surgical light does not raise any new safety or efficacy issues.

Summary of Nonclinical Testing: - This device conforms to lEC 60601-2-41:2001 specifications for performance of surgical lamps. Testing was conducted in accordance with this standard to support substantial equivalence. The ClaveGuard Freedom surgical light meets all requirements of the performance standard and achieved specified desired values per the product design specifications. Clinical testing was not required or utilized to support substantial equivalence

Summary of Safety and Effectiveness: Testing and evaluation indicate that the system meets the needs of the users of the device and does not raise any new safety and efficacy of the predicate device.
The ClaveGuard Freedom surgical light conforms to the

1. IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 “Medical Electrical Equipment- Part 1 General requirement for basic safety and essential performance.
2. IEC 60601-2-41:2009 Medical Electrical Equipment- Part 2-41: Particular requirement for basic safety and essential performance of surgical luminaires for diagnosis.
3. IEC 60601-1-2:2007 “Medical Electrical Equipment- Part 1-2 General requirement for basic safety and essential performance- Collateral Standard: Electromagnetic compatibility- requirement and test.

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4. IEC 60601-1-4:2000 “Medical Electrical Equipment- Part 1-4 General requirement for safety- Collateral Standard: Programmable Electrical Medical System.